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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/733,542 | 12/11/2003 | Stephen C. Wardlaw | 5169-0011-1-1 | 7739 |

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O'SHEA, GETZ & KOSAKOWSKI, P.C.
1500 MAIN ST.
SUITE 912
SPRINGFIELD, MA 01115

EXAMINER

BHAT, ADITYA S

ART UNIT PAPER NUMBER

2863

DATE MAILED: 06/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/733,542 | WARDLAW ET AL. | |
| | Examiner | Art Unit | |
| | Aditya S. Bhat | 2863 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,8-10,14 and 19-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,8-10,14 and 19-24 is/are rejected.
- 7) ☒ Claim(s) 1,5,19,20 and 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/14/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

With regards to claim 5, the word "of" in the amended portion of the claim is not necessary. (Claim 5, line 2) Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5, 8-10, 14 and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (USPN 4,858,154) in view of Harmon et al. (USPN 6,512,986)

With regards to claim 1, Anderson et al. (USPN 4,858,154) teaches a method for providing quality control in an analytical instrument, said method comprising the steps of:

sending one or more quality control specimens to a operator of the analytical instrument; (Col. 3, lines 16-25)

directly or indirectly communicating control data to the analytical instrument, wherein the control data includes characteristic values for the one or more quality control specimens; (Col. 4 lines 25-35)

analyzing the quality control specimen using the analytical instrument and thereby creating instrument analysis data; (Col. 3 lines 1-15),

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providing notice to an operator regarding the functional status of the analytical instrument. (Col. 3, lines 17-20).

With regards to claim 19, Anderson et al. (USPN 4,858,154) teaches a method for providing quality control in an analytical instrument, said method comprising the steps of:

sending one or more quality control specimens to a operator of the analytical instrument (Col. 3, lines 16-25);

directly or indirectly communicating control data to the analytical instrument, wherein the control data includes acceptable operating standards (Col. 4 lines 25-35);

analyzing the quality control specimen using the analytical instrument and thereby creating instrument analysis data (Col. 3 lines 1-15); and

providing notice to the operator regarding the functional status of the analytical instrument (Col. 3, lines 17-20).

With regards to claim 20, Anderson et al. (USPN 4,858,154) teaches a quality control system for analytical instruments, said system comprising:

one or more quality control specimens, each having one or more predetermined characteristic values and an identifier that can identify the quality control specimen (Col.3 lines 1-25);

an analytical instrument, having an analyzer for analyzing the one or more quality control specimens and thereby create instrument analysis data that includes one or more sensed characteristic values (Col. 4, lines 26-35) and

means for notifying an operator regarding the functional status of the analytical instrument (Col. 3, lines 17-20).

With regards to claim 24, Anderson et al. (USPN 4,858,154) teaches method for providing quality control in an analytical instrument, said method comprising the steps of:

providing one or more quality control specimens and control data that includes characteristic values for the one or more quality control specimens, to an operator of the analytical instrument; (Col. 3, lines 16-25)

analyzing at least one of the one or more quality control specimens and thereby creating instrument analysis data (Col. 3 lines 1-15), and

providing notice to the operator regarding the functional status of the analytical instrument (Col. 3, lines 17-20).

With regards to claim 2, Anderson et al. (USPN 4,858,154) teaches the evaluation being performed without operator input (Col. 8, lines 37-45).

With regards to claim 3, Anderson et al. (USPN 4,858,154) teaches the evaluation is performed using routines preprogrammed within the analytical instrument (Col. 8, lines 37-45).

With regards to claim 4, Anderson et al. (USPN 4,858,154) teaches the evaluation is performed using a remotely located instrument independent of the analytical instrument (Col. 8, lines 37-45).

With regards to claim 5, Anderson et al. (USPN 4,858,154) teaches the step of performing an evaluation within the analytical instrument of includes a comparison of

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the characteristic values for the one or more quality control specimens and one or more characteristic values created within the instrument analysis data (Col. 5, lines 1-5).

With regards to claim 8 Anderson et al. (USPN 4,858,154) teaches the control data is communicated to the analytical instrument from a remote source via an electronic communications connection (Col. 8, lines 37-45).

With regards to claim 9, Anderson et al. (USPN 4,858,154) teaches communicating to the analytical instrument that the quality control specimen is for quality control purposes (Col. 3, lines 50-67).

With regards to claim 10, Anderson et al. (USPN 4,858,154) teaches communicating to the analytical instrument that the quality control specimen is for quality control purposes is performed without operator input (Col. 8, lines 37-45).

With regards to claim 18, Anderson et al. (USPN 4,858,154) teaches the step of automatically providing notice to a service provider that a scheduled quality control procedure has not been performed within a predetermined period of time (Col.8, lines 37-45).

With regards to claim 19 Anderson et al. (USPN 4,858,154) teaches the step of providing a standardized utilizing quality control procedures (Col. 5, lines 4-6).

With regards to claim 22, Anderson et al. (USPN 4,858,154) teaches evaluating the sensed characteristic values of the instrument analysis data using the predetermined characteristic values does not require input from an operator (Col.8, lines 37-40).

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With regards to claim 23 Anderson et al. (USPN 4,858,154) teaches a standardized identifier displayed with the system that identifies the system as using quality control procedures (Col. 3, lines 3-15).

With regards to claims 1-3, 5, 8-10, 14 and 19-24, Anderson et al. (USPN 4,858,154) does not explicitly disclose an evaluation within the analytical instrument. Anderson et al. (USPN 4,858,154) reference does discuss an evaluation of a analytical instrument based on a performance index.

Harmon (USPN 6,512,986) discloses performing the evaluation within a analytical instrument. (Refer to figure 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the evaluation within a analytical instrument, in order to verify that the testing is performed properly. (Col. 3, line 55)

Anderson et al. (USPN 4,858,154) discloses the claimed invention except for performing the evaluation within a analytical instrument. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the evaluation within a analytical instrument, since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. In re Venner, 120 USPQ 192.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 19-20 and 24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, and 9 of patent 6,748,337. Although the conflicting claims are not identical, they are not patentably distinct from each other because the limitations of the claims in the current application are encompassed in the previous application. The latter pending application encompasses the same process as the pending application and is a slightly broader version of the previous application. (Underlined portions below, show the differences in the process). With regards to the amendments, the process is still the same and the claims read on each other in light of the specifications. It appears that performing the evaluation within the instrument would only automate the process. It would have been

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obvious to one having ordinary skill in the art at the time the invention was made to perform the evaluation within the instrument, since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. In re Venner, 120 USPQ 192.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

| Claim 1 (10/733542) | Claim 1 (6,748,337) |
|--|---|
| <p>1. A method for providing quality control in an analytical instrument, said method comprising the steps of: sending one or more quality control specimens to a operator of the analytical instrument; directly or indirectly communicating control data to the analytical instrument, wherein the control data includes characteristic values for the one or more quality control specimens; analyzing the quality control specimen using the analytical instrument and thereby creating instrument analysis data; <u>performing an evaluation within the analytical instrument of instrument analysis data using the control data to determine a functional status of the analytical instrument; and</u> providing notice to an operator regarding the functional status of the analytical instrument.</p> | <p>1. A method for providing quality control in an analytical instrument, said method comprising the steps of: sending one or more quality control specimens to a operator of the analytical instrument; directly or indirectly communicating control data to the analytical instrument, wherein the control data includes characteristic values for the one or more quality control specimens; analyzing the quality control specimen using the analytical instrument and thereby creating instrument analysis data; evaluating the instrument analysis data using the control data to determine a functional status of the analytical instrument; and providing notice to an operator regarding the functional status of the analytical instrument <u>wherein the control data is communicated to the analytical instrument by a machine readable label attached to the quality</u></p> |

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| | <u>control specimen.</u> |
| Claim 19 (10/733542) | Claim 2 (6,748,337) |
| <p>19. A method for providing quality control in an analytical instrument, said method comprising the steps of:</p> <p>sending one or more quality control specimens to a operator of the analytical instrument</p> <p>directly or indirectly communicating control data to the analytical instrument, wherein the control data includes acceptable operating standards</p> <p>analyzing the quality control specimen using the analytical instrument and thereby creating instrument analysis data</p> <p><u>performing an evaluation within the analytical instrument of the instrument</u> analysis data relative to the control data to determine a functional status of the analytical instrument and providing notice to the operator regarding the functional status of the analytical instrument</p> | <p>2. A method for providing quality control in an analytical instrument, said method comprising the steps of: sending one or more quality control specimens to a operator of the analytical instrument</p> <p>directly or indirectly communicating control data to the analytical instrument, wherein the control data includes <u>characteristic values for the one or more quality control specimens</u> analyzing the quality control specimen using the analytical instrument and thereby creating instrument analysis data evaluating the instrument analysis data using the control data to determine a functional status of the analytical instrument and providing notice to the operator regarding the functional status of the analytical instrument wherein the control data is communicated to the analytical instrument by a machine readable medium supplied with the quality control specimen.</p> |
| Claim 20 (10/733542) | Claim 9 (6,748,337) |
| <p>20. A quality control system for analytical instruments, said system comprising:</p> <p>one or more quality control specimens, each having one or more predetermined characteristic values and an identifier that can identify the quality control specimen</p> <p>an analytical instrument, having an analyzer for analyzing the one or more quality control specimens and thereby create instrument analysis data that includes one or more sensed characteristic values</p> <p>means <u>performing an evaluation within</u></p> | <p>9. A quality control system for analytical instruments, said system comprising: one or more quality control specimens, each having one or more predetermined characteristic values and an identifier that can identify the quality control specimen</p> <p>an analytical instrument, having an analyzer for analyzing the one or more quality control specimens and thereby create instrument analysis data that includes one or more sensed characteristic values means for evaluating the sensed characteristic values of the instrument analysis data using the predetermined</p> |

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| <p><u>the analytical instrument using the instrument analysis data and the predetermined characteristic values to determine a functional status of the analytical instrument; and means for notifying an operator regarding the functional status of the analytical instrument .</u></p> | <p>characteristic values to determine a functional status of the analytical instrument wherein the means for <u>evaluating the sensed characteristic values of the instrument analysis data using the predetermined characteristic values does not require input from an operator means for notifying an operator regarding the functional status of the analytical instrument and means for selectively preventing the reporting of test results in the event the functional status of the analytical instrument is determined to be unacceptable</u></p> |
| <p>Claim 24 (10/733542)</p> | <p>Claim 9 (6,748,337)</p> |
| <p>24. A method for providing quality control in an analytical instrument, said method comprising the steps of:</p> <p><u>providing</u> one or more quality control specimens and control data that includes characteristic values for the one or more quality control specimens, to an operator of the analytical instrument;</p> <p>analyzing at least one of the one or more quality control specimens and thereby creating instrument analysis data</p> <p><u>performing an evaluation within the analytical instrument of the instrument analysis data relative to the control data to determine a functional status of the analytical instrument and</u></p> <p>providing notice to the operator regarding the functional status of the analytical instrument</p> | <p>1. A method for providing quality control in an analytical instrument, said method comprising the steps of:</p> <p>sending one or more quality control specimens to a operator of the analytical instrument;</p> <p>directly or indirectly communicating control data to the analytical instrument, wherein the control data includes characteristic values for the one or more quality control specimens;</p> <p>analyzing the quality control specimen using the analytical instrument and thereby creating instrument analysis data;</p> <p><u>evaluating the instrument analysis data using the control data to determine a functional status of the analytical instrument; and</u></p> <p>providing notice to an operator regarding the functional status of the analytical instrument</p> <p><u>wherein the control data is communicated to the analytical instrument by a machine</u></p> |

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| | <u>readable label attached to the quality control specimen.</u> |
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Response to Arguments

Applicant's arguments filed 4/14/2005 have been fully considered but they are not persuasive.

During patent examination, the pending claims must be "given the broadest reasonable interpretation consistent with the specification." Applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. In re Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969).

While the meaning of claims of issued patents are interpreted in light of the specification, prosecution history, prior art and other claims, this is not the mode of claim interpretation to be applied during examination. During examination, the claims must be interpreted as broadly as their terms reasonably allowed. This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Applicant's arguments with respect to claims 1-3, 5, 8-10, 14 and 19-24 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Young et al. (USPN 6,509,192) teaches a Quality control method.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

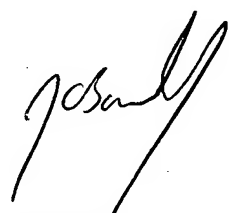
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditya S Bhat whose telephone number is 703-308-0332. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow can be reached on 703-308-3126. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-5841 for regular communications and 703-308-5841 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0956.

Aditya Bhat
June 20, 2005



John Barlow
Supervisory Patent Examiner
Technology Center 2800